

REMARKS

This paper is responsive to an Official Action that was issued in this case on October 5, 2007. In that Action, the Examiner withdrew the final rejection of claims 1-40 over U.S. Published Patent Application 2003/0031993 to Pugh and issued new rejections of claims 1-40 over Cunningham *et al.*

Responsive to the Action, applicant hereby amends claims 1, 4, 13, 21, 27, and 35. Reconsideration is respectfully requested in view of the foregoing amendments and the following comments.

Before addressing the specifics of the Examiner's rejections, it will be useful to briefly review the subject matter of this application. This case is one of a suite of five patent applications that are directed various aspects of a vascular access simulation system that has been developed by the applicant.

The Applicant is quite familiar with the Cunningham *et al.* reference upon with the Examiner now relies for her claim rejections. Indeed, a significant portion of the Background section of each of the five related cases is devoted to that system and its shortcomings. (Applicant's patent applications actually reference US. Pat. No. 6,470,302, which is the parent application of Published Patent Application relied upon by the Examiner.)

The patent application under consideration here is directed to ergonomic considerations of applicant's vascular access unit. As described in the Specification, and, in fact, as mentioned in some if not all of the related cases as well, a substantial contributor to the utility of a simulation system as a training tool is the extent to which it promotes or supports a user's "suspension of disbelief."

In other words, to the extent that a user is relatively less aware that the simulation system is not the "real" thing, the training experience is more realistic and, it is believed, more useful. And the ergonomics of the simulation system is a key factor contributing to a "suspension of disbelief;" either promoting it as in the claimed invention or undercutting it as in the device disclosed by Cunningham *et al.*

Applicant identified a number of ergonomic considerations or features that are believed to be important to promote a "suspension of disbelief" for a vascular-access simulation system. They include:

1. The profile of the haptics device should remain relatively low — advantageously not substantially higher than a person's arm when it is resting flat on a surface.

2. The shape of the haptics device should not be overtly inconsistent with human anatomy (e.g., an arm, etc.).
3. When practicing a vascular-access procedure using the haptics device, the position of a user's hands should be similar to the position of the hands when performing an actual vascular-access procedure.
4. The sites at which the palpation and skin stretch techniques are performed should be correct relative to one another (in terms of the sites of these techniques during an actual vascular-access procedure).
5. The sites at which the occlusion and skin stretch techniques are performed should be correct relative to one another (in terms of the sites of these techniques during an actual vascular-access procedure).
6. The sites at which the occlusion and skin stretch techniques are performed should be correct relative to the site at which the catheter/needle is inserted into the haptics device (in terms of the sites of these techniques during an actual vascular-access procedure).
7. The various mechanisms of the haptics device should be beneath the "skin" of the haptics device.

(See, Summary, at para. 0014.)

It is not known whether Cunningham *et al.* were aware of these ergonomic considerations. But the fact is that they are not features of the device that is disclosed by Cunningham *et al.* (See, e.g., "Background of the Invention" at paras. 0006-0010.) Nor are they otherwise obvious.

Applicant's device, on the other hand, exhibits one or more of these ergonomic features (in addition to any others). These features, which distinguish applicant's device from Cunningham *et al.* are recited, in one form or another, as limitations in many of applicant's claims.

Regarding the amendments to the claims, applicant has amended claims 1, 4, 13, 21, 27, and 35 to make it clear that the various skin-interaction mechanisms and receiver are covered by the pseudo skin. The claims previously recited that the mechanisms/receiver were "underneath" the pseudo skin. Although applicant intended this to mean "covered by," the Examiner was apparently reading the language "underneath" to mean simply "at a

lower level.” The added language is intended to make it clear that what is being claimed is that the various mechanisms are below and covered by the skin.

This positioning of the mechanisms and receivers relative to the pseudo skin is an important ergonomic consideration intended to promote the “suspension of disbelief” as previously discussed. Consider a practitioner about to insert a catheter into an actual human arm — all anatomical structures (e.g., vein, bone, muscle, etc.) are contained in the arm and “underneath” the skin.

It is evident from even a quick look at FIG. 3 (of the Cunningham *et al.*) that Cunningham *et al.* does not disclose this arrangement and, as a consequence, does not look even remotely like a portion of a person’s arm.

Turning now to the claims:

Amended Claim 1 recites an apparatus comprising:

<p>pseudo skin; a receiver, wherein said receiver receives an end effector; and a first device for performing a first skin-interaction technique that is used in conjunction with a simulated vascular-access procedure, wherein said receiver and said first device are disposed beneath said pseudo skin and are covered by said pseudo skin.</p>

Cunningham *et al.* does not disclose or suggest what is recited in amended claim 1. In particular, the receiver and first device are either not “beneath said pseudo skin” or they are not “covered by said pseudo skin.”

If Cunningham *et al.* discloses elements that are analogous to applicant’s claimed “receiver” and “first device,” they would be “shaft (44)” and “skin traction mechanism (36).” Although Cunningham *et al.* does not disclose a “pseudo skin” as that term is used by applicant, for the sake of discussion, “belt (108)” will be considered to be analogous to applicant’s claimed pseudo skin.

First, at least a part of the shaft (44) extends beyond the housing of the Cunningham *et al.* device at all times and is above the level of belt (108). Therefore, the receiver is not “beneath said pseudo skin.” Furthermore, there is no “pseudo skin” in the vicinity of the point in which shaft (44) extends from the housing. Therefore, the receiver is not “covered by said pseudo skin.”

Furthermore, the skin-traction mechanism (36) of Cunningham *et al.*, which enables a practitioner to practice the one skin-interaction procedure that can be performed on that device, is not, in fact, below a "pseudo skin." In particular, to the extent that belt (108) can be considered to be a "pseudo skin," the belt itself is actually a part of the skin-traction mechanism. (See, e.g., para. 0046: "The belt motion causes belt pulleys 112, 115 to rotate wherein rotation of belt pulley 112 is measured by potentiometer 114.") That being the case, that mechanism is not "disposed underneath said pseudo skin" or "covered by said pseudo skin," as required by claim 1.

In view of the foregoing, amended claim 1 is allowable over Cunningham *et al.* Claims 2 through 24 are allowable based on their dependence on claim 1. Furthermore, the recitation of additional patentable features in claims 2 through 24 provides a secondary basis for their patentability. As a consequence, applicant requests that the rejection of claims 1-24 be withdrawn.

Claim 25 recites an apparatus comprising:

a housing;
an end effector, wherein said end effector is inserted into said housing during the performance of a simulated vascular-access procedure; and
a plurality of mechanisms, wherein said plurality of mechanisms are contained completely within said housing, and wherein said plurality of mechanisms include:
(a) a first mechanism is for simulating a first skin-interaction technique that is used in conjunction with a simulated vascular-access procedure; and
(b) a second mechanism for receiving said end effector.

Among other limitations, claim 25 recites that the "end effector is inserted into said housing during the performance of a simulated vascular-access procedure." See, e.g., ergonomic consideration 7. See, *also*, para. 0039: "In an actual vascular-access procedure, the needle or catheter, of course, remains outside of the body until inserted during the procedure. Likewise, in accordance with the illustrative embodiment, the end effector — needle/catheter module **218**— remains outside of housing **216** and pseudo skin **220** until a portion of it is inserted during a simulated vascular-access procedure.

In the Cunningham *et al.* device, on the other hand, the end effector is NOT "inserted into said housing during the performance of a simulated vascular-access procedure." In

Cunningham *et al.*, before using the device to simulate a vascular-access procedure, the device must be initialized by inserting the catheter/needle assembly into shaft (44). The procedure can be practiced only after initialization. To practice needle/catheter insertion, the now-coupled shaft (44) and needle/catheter assembly (47) is manipulated as a whole.

Thus, BEFORE the simulation even begins (not during the simulation as per the claim), the end effector is inserted into the receiver. Placing a needle in the shaft to initialize the unit and *then* manipulating the combined needle and shaft as if the combination were the needle, does not realistically simulate a vascular-access procedure.

It is notable that in the Cunningham *et al.* device, the catheter tube (91) resides in shaft (44) at all times. (See, para. 0036, seventh sentence and Figure 5A.) The catheter tube (91) is thus part of the "end effector." Since it resides in shaft (44), and since shaft (44) remains partially within the housing at all times, the end effector is not, therefore "inserted therein during a simulated vascular-access procedure."

Furthermore, claim 25 recites "a plurality of mechanisms, wherein said plurality of mechanisms are contained completely within said housing." The claim further recites that the mechanisms comprise "a first mechanism is for simulating a first skin-interaction technique" and "a second mechanism for receiving said end effector."

As previously indicated, in the Cunningham *et al.* device, the mechanism for "receiving said end effector," which is shaft (44), is NOT "contained completely within said housing."

Also, it is quite evident that in the Cunningham *et al.* device, the mechanism for simulating a first skin interaction technique, which is the skin traction mechanism (36) is NOT "contained completely within said housing." In fact, the skin traction mechanism is completely OUTSIDE of the housing (case (32)). While the Examiner might argue that both the receiver and the skin traction mechanisms are contained in a housing — they are *different* housings. The language of the claim requires that both mechanisms are in the same housing. Again, this is an important ergonomic consideration.

In view of the foregoing, claim 25 is allowable over Cunningham *et al.* Due to their dependence on allowable claim 25, claims 26 through 34 are allowable. Furthermore, the recitation of additional patentable features in claims 26 through 34 provides a secondary

basis for their patentability. As a consequence, applicant requests that the rejection of claims 25-34 be withdrawn.

Amended claim 35 recites an apparatus comprising:

<p>a pseudo skin; a plurality of mechanisms with which a user interacts for simulating a vascular-access procedure, including at least one mechanism for performing a skin-interaction technique, wherein said plurality of mechanisms are disposed under said pseudo skin and are covered by said pseudo skin; and a housing, wherein said housing contains said plurality of mechanisms.</p>
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Cunningham *et al.* does not disclose what is recited in amended claim 35. As previously explained, in the Cunningham *et al.* device, a plurality of mechanisms for simulating a vascular-access procedure (including a mechanism for performing a skin interaction technique) are not covered by pseudo skin. Furthermore, these mechanisms are NOT all within the housing.

In view of the foregoing, claim 35 is allowable over Cunningham *et al.* Due to their dependence on allowable claim 35, claims 36 through 40 are allowable. Furthermore, the recitation of additional patentable features in claims 36 through 40 provides a secondary basis for their patentability. As a consequence, applicant requests that the rejection of claims 35-40 be withdrawn.

CONCLUSION

In view of the foregoing amendments and arguments, it is believed that claims 1-40 now presented for examination are allowable over the art of record. A notice to that effect is therefore requested.

Respectfully,
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